

Appl. No. 09/717,641  
Amdt. Dated May 9, 2005  
Response to Office Action mailed on September 8, 2004

Patent Docket P0645P4D2C3

### REMARKS

#### Formal Matters

Claims 89, 91-100 remain in this application. Claims 1-88 and 90 have been canceled.

#### Priority

The Examiner alleges that the priority application filed April 10, 1991 (US Seri. No. 07/683,400) does not provide adequate support under 35 U.S.C. 112 for claims 89 and 91-100, specifically, with respect to the phrase "a suppressible termination codon is between or adjacent to the first and second genes." Applicants respectfully reiterate the traversal in the response of record of June 29, 2004.

The Examiner explained in the Office Action of September 8, 2004 that his determination of said absence of support was based on the Examiner's review of Application 07/621,667, instead of the above-referenced Application No. 07/683,400 itself. In this instance, application No. 07/683,400, is the specific prior application to which Applicants claim priority for the aforementioned phrase. Therefore, Applicants submit that the appropriate basis for the Examiner's review is this specific application, not a different application in the priority chain. As Applicants pointed out previously, support for the pending claims can be found at least at, *inter alia*, page 20, lines 15-21; page 21, lines 19-22; and page 21, lines 32-36, of Application 07/683,400 filed April 10, 1991. Therefore, the pending claims are entitled to a priority at least as early as April 10, 1991. The Office's acknowledgment of such is respectfully requested.

For the Examiner's convenience, Applicants have provided the relevant marked-up pages of the aforementioned priority application 07/683,400 along with an annotated first page as "Attachment A" to this response.

#### Rejection Under 35 U.S.C. § 103(a)

Present claims 89, 91-100 as they currently stand are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Huse (U.S. Pat. No. 5,770,434) as applied to claim 89-91, 93 and 94, in view of Ladner et al. (US Pat. No. 5,223,409). Applicants respectfully traverse.

As discussed in Applicants' response of June 29, 2004, Huse does not teach all the limitations of the claimed invention, and Ladner et al. does not cure the deficiency.

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The Examiner has acknowledged that Huse does not teach using just a portion of a phage coat, nor does it teach the use of the gIII coat protein. See Office Action, page 4. The Examiner alleges that Ladner teaches using portions of the phage coat proteins in the fusions. The Examiner points to Ladner at column 109, lines 10-23 and column 108, lines 42 on to column 109, line 23 to support his contention that "both the gIII signal peptide (lacking the C-terminal portion of the coat protein) and the mature gVIII peptide (lacking the N-terminal signal sequence) represent portions of coat proteins...."

Applicants respectfully submit that the Examiner has mischaracterized Ladner's teaching. Applicants respectfully point to, for example, Figure 1 of Ladner and its corresponding description at column 12, line 55 to column 13, line 5, in which Ladner clearly differentiates "precoat protein" from "coat protein". Ladner refers to coat protein, wild type or chimeric, *with the addition of the signal peptide* as "precoat protein", thereby distinguishing a precoat protein from one in which the signal peptide has been cleaved off to generate a "coat protein". This description provides the proper context for understanding the language pointed to by the examiner, as there is a discussion (starting at Column 109, line 24) of Figure 1 directly following the Examiner's cited text, discussing mechanism by which the coat proteins are directed for surface expression.

It is worth noting that as shown in Figure 1 of Ladner, the signal peptides which the Examiner improperly refer to as portions of coat protein remain in the cytoplasm and do not express on the surface, a characteristic the Examiner appears to acknowledge as desirable for coat proteins generally. Indeed, Ladner teaches that these signal peptides or sequences are actually degraded. See, e.g., column 110, line 6.

Applicants further respectfully submit that Ladner does not provide a specific enabling teaching of a gene fusion, comprising a first gene encoding a first polypeptide, a second gene encoding a *portion* of a phage coat protein.

Applicants further respectfully submit that there is no motivation or expectations of success for combining the teachings of Huse and Ladner. Huse does not motivate or suggest the combination of its teachings with the teachings of Ladner. Ladner has no teaching as to the addition of a suppressible termination codon to a fusion protein, nor does it provide any motivation or suggestion to make such a modification. To the contrary, in discussing other references which disclosed addition of codons (e.g., as spacers), Ladner noted that these references "taught away" from Ladner's teachings that relate to constraining the conformational repertoire of mutated residues relative to the coat protein in a fusion

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polypeptide. See, e.g., Ladner, column 6, lines 6-17. Therefore, the Examiner's own cited reference intrinsically teaches away from the incorporation of intervening codons between a first gene encoding a first polypeptide and a second gene encoding a portion of a phage coat protein. Therefore, Applicants respectfully submit that the Office has not satisfied the requirement of *prima facie* obviousness.

In view of the above, withdrawal of the instant rejection is respectfully requested.

**Obviousness-type double patenting rejection**

Claims 89 and 91-100 are rejected for obviousness-type double patenting as allegedly being unpatentable over claims 1, 6, 7 and 14 of U.S. Pat. No. 6,040,136. Claims 89 and 91-100 are rejected for obviousness-type double patenting as allegedly being unpatentable over claims 32-34 of U.S. Pat. No. 5,750,373.

Applicants again refer the Examiner to Applicants' response of June 29, 2004, where, without acquiescing to the instant rejection, Applicants stated they will execute a terminal disclaimer upon an indication of allowable subject matter in order to expedite allowance of the instant case.

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**SUMMARY**

Claims 89 and 91-100 are pending in the application. Claims 1-88 and 90 are canceled without prejudice to later prosecution.

If in the opinion of the Examiner, a **telephone conference** would expedite the prosecution of the subject application, the Examiner is **strongly encouraged** to call the undersigned at the number indicated below.

This amendment is submitted with a transmittal letter and petition for a one-month extension of time and fees. In the unlikely event that this document is separated from the transmittal letter or if fees are required, applicants petition the Commissioner to authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,  
GENENTECH, INC.

Date: *May 9, 2005*

By: 

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Attachment A (3 pages)